5. 510(k) Summary

Rayner

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Rayner Intraocular Lenses Limited
1-2 Sackville Trading Estate, Sackville Road
Hove, East Sussex
England
BN3 7AN
Telephone: 44-1273-205401
Fax: +44 (0) 1273 324623
www.rayner.com

Date this summary prepared: 20th March 2013

Devices

Common Name: Rayner Injectors

Trade/Proprietary names:

Single Use Soft Tipped Disposable Injector (Model R-INJ-04)

and

Raysert Single Use Soft Tipped Small Incision Disposable Injector

(Model R-INJ-04/18)

CFR section:	Title 21 Part 886 Subpart E Section 886.4300 Intraocular Lens Guide
Classification Name:	Intraocular lens guide
Product code:	MSS
Device Class:	Class I
Classification Panel:	Ophthalmic

Information on devices to which substantial equivalence is claimed

510(k) number:	K091507
Trade/Proprietary name:	Single Use soft tipped injector R-INJ-04/18
Manufacturer:	Rayner Intraocular Lenses Limited, Sackville Road, Hove, East Sussex, BN3 7AN; United Kingdom

Official Correspondent:
Juliette E Cook
Rayner Intraocular Lenses Limited
1-2 Sackville Trading Estate, Sackville Road
Hove, East Sussex
BN3 7AN
United Kingdom

Phone: +44-1273-205401

US Agent:
Robert Mazzaferro
RegTech Solutions LLC
11 Dellcastle Court
Montgomery Village
MD 20886

Phone: 301 2162720

Model R-INJ-04 and Model R-INJ-04/18

5.1 Intended Use

The single use disposable injectors (Model R-INJ-04 and Model R-INJ-04/18) are intended to be used to compress and insert into the capsular bag only those intraocular lenses that allow the use of these injectors in their approved labelling.

5.2 Description of the device that is subject of the application

There are two types of Rayner disposable single use soft tipped injectors (Model R-INJ-04 and Model R-INJ-04/18). They are the same except Model R-INJ-04 has a 2.0 mm diameter nozzle and Model R-INJ-04/18 has a 1.8 mm nozzle. The size is indicated on the barrel flap of the respective injectors by 1.8 or 2.0 embossed texts.

The injectors are assembled from a nozzle, barrel, flap, guide bushes and plunger components which are made of polypropylene material. The plunger has a thermoplastic elastomer soft tip at one end.

The injectors are supplied sterile.

5.3 Comparison of technological characteristics to a predicate device

The intended use of the predicate device and the Models subject of this traditional 510(k) is the same: "intended to be used to compress and insert into the capsular bag only those intraocular lenses that allow the use of these injectors in their approved labelling.

The predicate device applies the same operating principle to implant the lens into the eye. The predicate device is similar to the modified injectors described in this submission. There is no significant difference between the devices; the predicate device has similar technical characteristics, such as design, components, materials, assembly method and intended use. The difference between the two injector models described in this submission (Model R-INJ-04 and R-INJ-04/18), can be summarised as the diameter of the nozzle, 1.8mm and 2.0mm respectively and the nozzle diameter in text embossed on the barrel flap. The predicate device has a 1.8 mm nozzle.

The predicate and substantially equivalent devices have passed tests in accordance with standards. Tests and studies were completed to demonstrate that lenses implanted with the Rayner injectors sustain mechanically and optically uncompromised characteristics, compared to the predicate.

There are no significant differences in the features between the predicate and substantially equivalent devices that could adversely affect the safety and/or performance of the injectors or the lenses implanted with these devices.

5.4 Non-clinical performance data

The substantial equivalence of the Rayner injectors (Model R-INJ-04 and Model R-INJ-04/18) with the predicate device is based on the assessment of the technical characteristics, such as design, components, materials, assembly method and intended use of the injectors and test results performed.

The test results demonstrate that the modified Rayner Injectors (Model R-INJ-04 and Model R-INJ-04/18) deliver into the eye those lens models that allow use of these injectors in their approved labelling with no significant impact on the optical and mechanical performance or dimensions or the cosmetic features of the lenses.

The following paragraphs summarise the non-clinical tests that demonstrate that the Rayner injectors (Model R-INJ-04 and Model R-INJ-04/18) are safe, effective and perform as well as (or better than) the predicate device (CFR Part 807.92(b)(3)).

The tests include:

- Injector biocompatibility tests
- Sterilisation validation
- Visual, mechanical and optical testing of the injected lens
- Visual and mechanical testing of the disposable Rayner injectors
- Packaging performance testing and stability studies

These tests demonstrate that when the devices are used according to the manufacturer's instructions, the injectors perform to the pre-determined specifications.

Injector biocompatibility tests

The material of **all components** of the **predicate device** is the **same polypropylene material as** the polypropylene material of **all components of the Rayner Injectors (Model R-INJ-04 and Model R-INJ-04/18),** and it has not been changed.

The points of contact with the patient are the injector nozzle and the plunger. Biocompatibility tests on these components have been carried out on the predicate device. In summary, all tests were passed and the data demonstrate that the materials of Rayner injectors (Model R-INJ-04 and Model R-INJ-04/18) are biocompatible and toxically safe to be used as intended by the manufacturer. There has been no material change to the predicate device since it was 510(k) cleared.

Other components of the injector are not in contact with the patient, nor with the user.

Sterilisation Validation

The injectors are packed in the primary packaging and sterilised at Sterigenics UK Ltd. The sterilisation process was validated and achieved SAL 10^{-6}. The method of ethylene-oxide (ETO) sterilisation process is the same as for the predicate device.

Visual, mechanical and optical testing of the injectors and the injected lenses

The visual, mechanical and optical criteria of the device performance, such as cosmetic defects, MTF, power, compression force, surface finish and dimensions were identified as per ISO 11997-3. These criteria were met. Pre and post injection visual, mechanical and optical tests have been completed on lenses injected using the disposable Rayner injectors (Model R-INJ-04 and Model R-INJ-04/18) with satisfactory results.

Pre and post injection visual tests were carried out for:

- Optic damage or tear on lenses loaded in accordance with manufacturer's description
- Damage to the lens haptic
- Folding lines, deposits or debris transferred to the lens

Optical test

- Modulation Transfer Function (MTF)
- Dioptric power

Mechanical testing

- Dimensions
- Lens sagittal dimension
- Lens overall diameter
- Aperture opening test
- Injection force testing
- Visual and mechanical testing of the disposable Rayner injectors

The visual, mechanical and optical criteria of the device performance, such as cosmetic defects, MTF, power, compression force, surface finish and dimensions were identified as per ISO 11997-3. These criteria were met.

- Surface finish
- Cosmetic inspection
- Nozzle-tip detachment from barrel

Packaging performance testing and stability studies

- Sterility test
- Dye penetration
- Burst test

5.5 Overall conclusion of the Non-clinical performance data

There are no significant differences in the features between the predicate and substantially equivalent devices that could adversely affect the safety and/or performance of the injectors or the lenses implanted with these devices.

The tests carried out on the predicate device and Model R-INJ-04 and Model R-INJ-04/18 confirm that the Rayner injectors are safe and perform as intended by the manufacturer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 27, 2014

Rayner Intraocular Lenses, Ltd.
% Mr. Hans-Gerd Evering
Lead Technical Reviewer, BSI Assurance UK Limited
Kitemark Court, Davy Avenue, Knowlhill
Milton Keynes, MK5 8PP, UK

Re: K132002
Trade/Device Name: Single Use Soft Tipped Disposable Injector (Model R-INJ-04) and Raysert Single Use Soft Tipped Small Incision Disposable Injector (Model R-INJ-04/18)
Regulation Number: 21 CFR 886.4300
Regulation Name: Folders and Injectors, Intraocular Lens (IOL)
Regulatory Class: Class I
Product Code: MSS
Dated: February 28, 2014
Received: March 13, 2014

Dear Mr. Evering:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. Indications For Use Statement

510(k) Number (if known):K132002

Device Name: **Rayner Injectors**

Single Use Disposable Soft Tipped Injector (Model R-INJ-04)

and

Raysert Single Use Soft Tipped Small Incision Disposable Injector (Model R-INJ-04/18)

Indications For Use:

Statement of Indications For Use

The single use disposable injectors (Model R-INJ-04 and Model R-INJ-04/18) are intended to be used to compress and insert into the capsular bag only those intraocular lenses that allow the use of these injectors in their approved labelling.

Prescription Use ____✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Tieuvi H. Nguyen -A
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